February 16, 2021

Smisson-Cartledge Biomedical LLC
Julie Stephens
Correspondent
111 Laurel Ridge Drive
Alpharetta, Georgia 30004

Re: K052055
Trade/Device Name: Smisson-Cartledge TIS-1200 Thermal Infusion System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion pump
Regulatory Class: Class II
Product Code: LGZ, FRN, FPA

Dear Julie Stephens:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated January 10, 2017. Specifically, FDA is updating this SE Letter because FDA has identified an additional product code to more clearly categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact CAPT Alan Stevens, OHT3: Office of GastroRenal, ObGyn, General Hospital and Urology Devices, (301) 796-6294, Alan.Stevens@fda.hhs.gov.

Sincerely,

Alan M. Stevens -S3

CAPT Alan Stevens
Acting Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

JAN 1 0 2017

Smisson-Cartledge Biomedical, LLC
C/O Ms. Julie Stephens
Consultant for Smisson-Cartledge Biomedical, LLC
Regulatory Resources Group, Incorporated
111 Laurel Ridge Drive
Alpharetta, Georgia 30004

Re: K052055
Trade/Device Name: Smisson-Cartledge TIS-1200 Thermal Infusion System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: LGZ, FRN
Dated: October 18, 2006
Received: October 19, 2006

Dear Ms. Stephens:

This letter corrects our substantially equivalent letter of October 26, 2006.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809]), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052055

Device Name: Smisson-Cartledge TIS-1200 Thermal Infusion System

Indications For Use:

Full range from slow feed to rapid, high flow infusion of:

- crystalloid, colloid, or blood product, including packed red blood cells, as volume replacement for patients suffering from blood loss due to trauma or surgery
- warmed fluid to rewarm patients after surgery or for hypothermia
- warmed fluid for irrigation in urology procedures

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[illegible]
[illegible] Division of Anesthesiology, General Hospital,
[illegible] Control, Dental Devices

[illegible] 10/25/06

Smisson-Cartledge Biomedical LLC

Exhibit J - 510(k) SUMMARY

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements under 21 CFR 807.92.

Submitted By: Smisson-Cartledge Biomedical LLC
502 Mulberry Street, Second Floor
Macon, GA 31201
Phone: (478) 744-9992

Contact Person: Julie Stephens, President/Consultant
Regulatory Resources Group, Inc.

510(k) Number: K052055

Date Prepared: July 26, 2005

Device Name and Classification:

Trade/Proprietary Name:	Smisson-Cartledge TIS-1200 Thermal Infusion System
Common Name:	Infusion Pump
Classification Name:	Infusion Pump
Product Code:	LGZ; FRN; FPA

Legally Marketed Predicate Device:

Belmont Fluid Management System (FMS2000) - 510(k) # K032778, K032674, K992672, K983975, K972284
Smiths Level 1® H-1200 Fast Flow Fluid Warmer System - 510(k) # BK020043

Device Description:

The Smisson-Cartledge TIS-1200 Thermal Infusion System is a portable tabletop or pole-mount device intended for use in the ambulance, medical helicopter, hospital emergency room and operating room environments. (See Exhibits A and B for photographs and drawings) The system consists of an infusion device and a compatible single-use sterilized disposable set with supply lines capable of interfacing with intravenous (IV) bags or optional-use cardiotomy equipment. It also includes a footswitch to allow hands-free user-controlled stopping and starting of fluid delivery. The Smisson-Cartledge TIS-1200 Thermal Infusion System is a volumetric pump capable of continuous infusion (up to approximately 100 L at a rate of from 10 mL per hour to 1200 mL per minute) and discrete bolus delivery. When the system is set to Bolus mode, the user can select a predetermined delivery volume and a default or adjustable rate and deliver a fixed bolus of up to 1 L. When connected to alternating current (AC) power, the Smisson-Cartledge TIS-1200 Thermal Infusion System can deliver fluids at body temperature in certain modes. It can also be set to run on battery power with heating capabilities disabled to allow transport of the patient. A lithium-ion battery pack provides power backup. The unit (infusion pump) and Large Volume Reservoir Holder are provided non sterile. The Disposable Cassette Kit and Large Volume Reservoir are provided sterile, non-pyrogenic and are single-use only. They are sterilized by Ethylene Oxide (EO) sterilization method.

Exhibit J - 510(k) SUMMARY

Indications for Use:

Full range from slow feed to rapid, high flow infusion of crystalloid, colloid, or blood product, including packed red blood cells, as volume replacement for patients suffering from blood loss due to trauma or surgery. Full range from slow feed to rapid, high flow infusion of warmed fluid to rewarm patients after surgery or for hypothermia. Full range from slow feed to rapid, high flow infusion of warmed fluid for irrigation in urology procedures.

Similarities and Differences to the Predicate Devices:

Similarities

The Smisson-Cartledge TIS-1200 Thermal Infusion System has the same basic mechanical characteristics to infuse and warm liquid products into a patient as the predicate devices, and the indications for use are the same as the Belmont predicate device.

Differences

The Smisson-Cartledge TIS-1200 Thermal Infusion System utilizes different materials from the predicate devices; however, the materials are biocompatible.

Summary of Testing:

The Smisson-Cartledge TIS-1200 Thermal Infusion System has the same indications for use, principles of operation, and mechanical characteristics as the predicate devices that were previously cleared for market under a 510(k). These conclusions were verified in performance / bench testing as summarized within the 510(k).

The Smisson-Cartledge TIS-1200 Thermal Infusion System device differs only in its materials used. All biocompatibility testing, as required, complies with ISO-10993 “Biological Evaluation of Medical Devices”.